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Patent

Case No.: 48317US030

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PATENT TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	JAPUNTICH, DANIEL A.		
Application No.:	09/678580	Group Art Unit:	3761
Filed:	October 3, 2000	Examiner:	Aaron J. Lewis
Title:	FIBROUS FILTRATION FACE MASK HAVING A NEW UNIDIRECTIONAL FLUID VALVE		

BRIEF ON APPEAL

Board of Patent Appeals
and Interferences
Commissioner for Patents
Washington, DC 20231

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on:

January 17, 2003
Date

Signed by: Earl G. Hanson

Dear Sir:

This is an appeal from the Office Action mailed on October 10, 2002 This Brief is being filed in triplicate. The fee required under 37 CFR § 1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

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I. Real Party In Interest

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

II. Related Appeals And Interferences

There is a related appeal in U.S. Patent Application Serial Nos. 08/240,877.

III. Status Of Claims

Claims 34-58 and 60-75 are pending in this application and are the subject of this appeal.

IV. Status Of Amendments

No amendments have been filed after the final rejection.

V. Summary Of The Invention

Persons who work in contaminated environments commonly wear filtering face masks over their nose and mouth to protect themselves from inhaling airborne pollutants. Many known filtering face masks have employed a cup-shaped mask body that includes a filter layer and that is adapted to fit over a wearer's nose and mouth. Exhalation valves have been used on these masks to rapidly purge exhaled air from the mask interior. The rapid removal of exhaled air makes the mask more comfortable to wear.

Because exhalation valves are powered by a wearer's lungs, valves that open easier during each exhalation improve wearer comfort because less work is needed to operate the valve. Valves that open easier also are beneficial in that they more rapidly purge warm, moist, exhaled from themask interior. In the working examples of the present invention, the applicants demonstrated that they were able to remove so much air (>100%) from the mask interior during a simulated exhalation, that an influx of cool ambient air occurred during the exhalations. For filtering face masks that had porous mask bodies, this was quite an achievement because it demonstrated, for the first time, that a filtering face mask could operate as a cool-air aspirator — drawing cool, low humidity, air into the mask interior through the filter media to substantially improve wearer comfort (see Examples 7-13). No prior art exhalation valve on a filtering face mask had yet demonstrated such a feat during an exhalation.

The most common type of exhalation valve that has been used on a filtering face mask is a "button-style" valve. These valves typically have a circular flexible flap that is mounted to a valve seat through a central stake or button. The whole circumference of the flap is generally free to be lifted from the seal surface during an exhalation. An example of a button-style valve is shown from the side in Figure 3 of UK patent application GB 2,072,516A to Simpson:

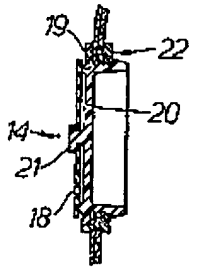

FIG. 3.

[Simpson Button-Style Valve]

Another example of a button-style valve is shown in U.S. Patent 4,873,972 to Magidson et al., assigned to Moldex/Metric Products Inc. and issued on October 17, 1989.

In addition to button-style valves, other valve structures have been used to purge exhaled air from the mask interior. For example, U.S. Patent 4,934,362 to Braun describes a valve, which when viewed from the side, has a parabolic valve seat. Like the button-style valves, the Braun valve has its flap mounted centrally to the valve seat. This central mounting, however, can interfere with the flow of exhaled air through the valve and does not allow as great a moment arm to be achieved in lifting the flap from the seal surface. Centrally-mounted valves also can cause exhaled air to be diverted into multiple flow streams.[1]

As an alternative to these centrally-mounted valves, a "flapper-style" or "cantilevered" valve also had been disclosed as being suitable for use on filtering face masks. Figure 2 of the Simpson patent shows such a valve:

[1] Examples 4-6 in applicants' specification show the performance of the Braun valve compared to applicants' invention.

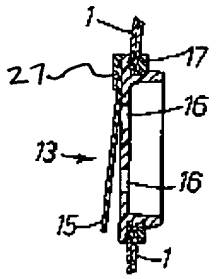

FIG. 2.

[Simpson Flapper Valve]

This flapper-style valve includes a "flexible circular flap member 15 of, for example, plastics material, which is arranged to cover and close valve opening 16 during an inhalation and to flex away from those openings during exhalation." To enable the flap member to flex, "a part of its peripheral portion, a segment of the flap member, is fixed in position, the remaining part of the flap member being left free." See Simpson at page 2, lines 37-46.

Although Simpson's flapper-style valve can provide a greater moment arm in lifting the flap 15 from the seal surface to encourage quick displacement of exhaled air from the mask interior, the valve does suffer from a number of deficiencies, amongst them, the inability to keep the flap closed under any orientation of the valve. To apparently keep its valve closed under neutral conditions — that is, when a wearer is neither inhaling nor exhaling — Simpson places the valve 12 on the top portion 1 of its duck-billed mask:

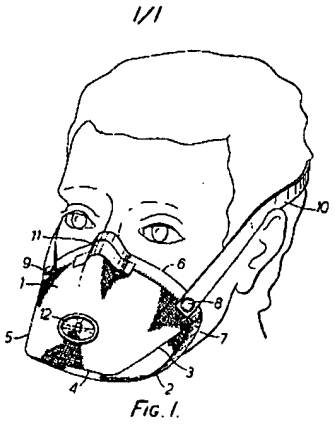

FIG. 1.

[Simpson Mask]

Simpson does not describe how to construct a flapper-style valve where the flap is pressed against a seal surface when a wearer is neither inhaling or exhaling. Simpson's valve relies on

gravity for this purpose. This reliance on gravity, however, places limits on the locations where Simpson's valve could be disposed on a cup-shaped mask without risking an influx of contaminants into the mask interior when a wearer is neither inhaling nor exhaling. And when the valve is not disposed directly in (or normal to) the path of the exhaled flow stream, the flap cannot fully take advantage of the momentum of the exhale flow stream during an exhalation to encourage more rapid and complete opening of the valve. Without this ability, displacement of exhaled air cannot be maximized, and aspiration effects are less likely to occur. In addition, because the Simpson valve does not have a pre-load on it, there is a great risk that the valve could remain open. Saliva and moisture commonly builds up on exhalation valves during use. The presence of these substances on the flap can cause the it to stick to another surface such as a valve cover when the flap comes open as a result of a force from an exhalation, or in Simpson's case from mere gravity. If the valve stays open, then contaminants can be direct drawn into the wearer's respiratory system during the next inhalation. Simpson recognizes that its valve may leak and suggests the use of an "antechamber" to prevent inhalation of "harmful atmosphere". See Simpson at p. 1 lines 58-64.

Applicants' filtering face mask includes a new exhalation valve 14 that is different in structure from and in performance over known exhalation valves:

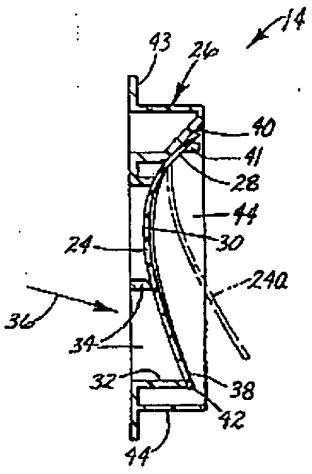

Fig. 3

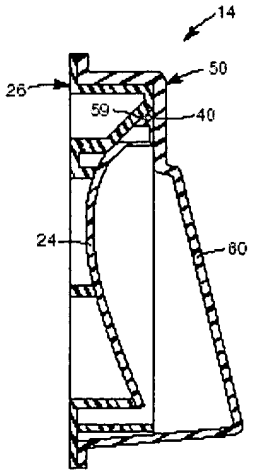

Fig 8

[Appellants' Valve]

Applicants' exhalation valve 14 includes a single flexible flap 24 that has a stationary portion 28, one free portion 38, and a circumferential or peripheral edge that includes (i) a stationary free

segment that is associated with the stationary portion 28 of the flap 24 so as to remain in substantially the same position during an exhalation and (2) a free segment that is associated with the free portion 38 of the flap so as to be movable during an exhalation (page 7, lines 15 to line 26). Like the Simpson valve, the free segment of the peripheral edge is disposed beneath the stationary segment when the valve is viewed from the front in an upright position (Fig. 1). Unlike Simpson's flapper-style valve 13, however, appellants' valve 14 includes a valve seat 26 that has a flap-retaining surface 40 and a seal surface 31, wherein the flexible flap 24 is mechanically held against the flap-retaining surface 40 by a surface 59 on the valve cover 50 (page 15, lines 14-16 and Fig. 8) and is positioned relative to the seal surface 31 such that the flap 24 is pressed towards the seal surface 31 in a substantial abutting relationship therewith under any orientation of the valve 14 when a fluid 36 is not passing through the orifice (page 9, lines 14-16).

This use of surface 59 on the valve cover to mechanically hold the flap 24 against the flap-retaining surface on the valve seat, in conjunction with the relative positioning of the seal surface 31 and the flap-retaining surface 40, allows the one free portion 38 of the flexible flap 24 to be pressed against the seal surface 31, under any orientation of the valve, when a wearer of the mask is neither inhaling nor exhaling. Although pressed against the seal surface to prevent the unwanted influx of contaminants, the flap's one free portion 38 can be readily lifted from the seal surface during an exhalation (as a bent cantilever) to allow large quantities of air to be rapidly purged from the mask interior (see appellants' specification at page 6, line 25 to page 9, line 29; see also Examples 4-13). The structure and benefits of applicants' invention are neither taught nor suggested in Simpson, which is the primary reference that has been cited against the appellants in this appeal; nor is this feature taught or suggested in U.S. Patent 1,701,277 to Shindel, a secondary reference cited against the applicants.

Although the different structure and benefits of applicants' invention have not been taught in the prior art, they have, however, been utilized by investigators in this field after publication of applicants' invention. For example, Magidson — an inventor of the subject matter used in the '972 Moldex patent mentioned above — described the use of a button-style valve on a filtering face mask in a 1988 patent application, but after the publication of appellants' invention, Magidson (in U.S. Patent 6,047,698 to Magidson et al. also assigned to Moldex-Metric Inc. and

filed on August 20, 1998) describes a flapper-style valve that has a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against a flap-retaining surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve. This subsequently developed product allows the flap "to be contoured to have a gentle curve inward and completely around the circumference of the valve seat 22":

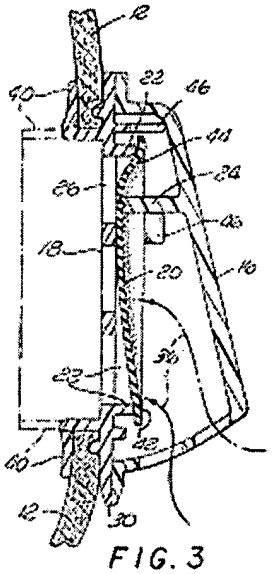

FIG. 3

[Magidson Valve]

As shown, the valve cover 16 has a surface on arm 24 that "extends down inside the seat 22 to capture the flap 20 against the portion 26." See the '698 patent at column 2, lines 33-40. Thus, while investigators in the pertinent field did not appreciate the structure and function of the appellants' invention before it was published, these same investigators did choose to adopt it after it became publicly known.

VI. Issues On Appeal

Issue 1

Appellants' claims 34-36, 50-56, 58, and 60-75 have been rejected based on a combination of Simpson and Shindel. Simpson describes a flapper-style exhalation valve for a filtering face mask where its flap is secured to the valve seat through the use of a part 27. Shindel describes a valve cap that has interior offsets 14 to press a rim portion 6 of the valve to

its seat.[2] Although neither document teaches or suggests the structure needed to provide a flexible flap that is pressed towards the seal surface in a substantial abutting relationship with it under any orientation of the valve, would the combination of Simpson and Shindel have nonetheless rendered appellants' invention obvious to a person of ordinary skill?

Issue 2

While Simpson and Shindel disclose respiratory face masks that use flexible flaps and operate under temperatures and pressures generated by a human's respiratory system at a person's breathing pace (typically 20 to 60 cycles per minute), a U.S. Patent 3,191,618 to McKim describes a curved seat reed valve for a two-cycle engine that operates at internal combustion temperatures and pressures and at speeds on the order of 10,000 to 20,000 revolutions per minute (rpms).[3] McKim's reed valve is made of spring sheet material such as shim stock, but the valve has a non-aligned seal surface and is structured to bias the reed valve towards it. Would Simpson, Shindel, and McKim, have rendered the subject matter of claims 37-49 obvious to a person of ordinary skill under the terms of 35 USC § 103?

VII. GROUPING OF CLAIMS

With the exception of claims 37-39, the appealed claims will stand or fall together with the independent claims. No admission is made, however, with respect to the patentability of the other dependent claims.

VIII. ARGUMENTS OF APPELLANTS

Issue 1 - Obviousness Based on Simpson and Shindel

Applicants' invention pertains to face mask 10 that comprises (a) a mask body 12 that is adapted to fit over the nose and mouth of a person and (b) an exhalation valve 14 that can be attached to the mask body 12 directly in front of where the wearer's mouth would be when the mask is worn:

[2] See page 15 of applicants' Brief for a discussion of Shindel.
[3] See page ____ of applicants' Brief for a discussion of McKim.

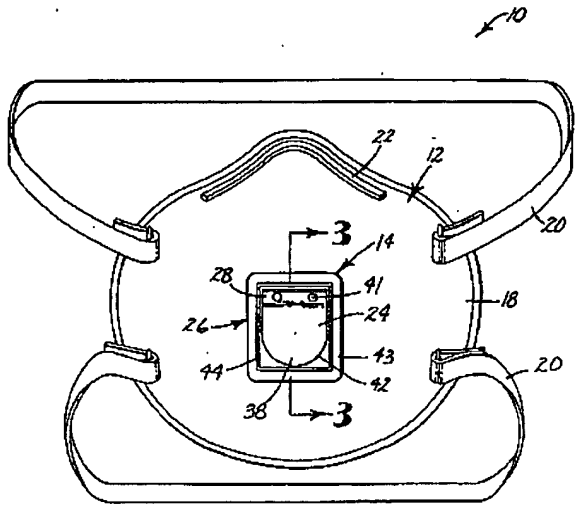

Fig. 1

[Applicants' Mask]

The exhalation valve 14 comprises a valve seat 26, a single flexible flap 24, and a valve cover 50 (Fig. 8). The valve seat 26 comprises an orifice 32, a seal surface 31 that surrounds the orifice 32, and a flap retaining surface 40:

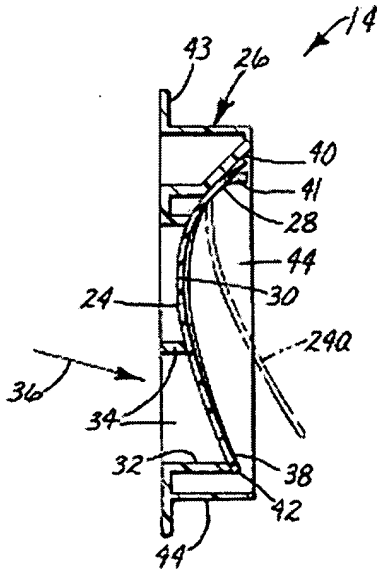

Fig. 3

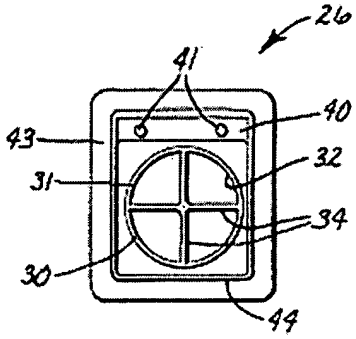

Fig. 4

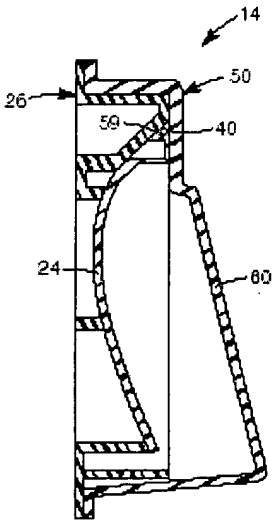

Fig 8

[Applicants' Valve]

A valve cover 50 is disposed over the valve seat and has a surface 59 that mechanically holds the flexible flap 24 against the flap-retaining surface 40. The flexible flap is held against the flap-retaining surface 40 and is positioned relative to the seal surface 31 such that the flap 24 is pressed towards the seal surface 31 in a substantial abutting relationship with it under any orientation of the valve when a fluid 36 is not passing through the orifice 32. Appellants' invention is different from valves that were previously known in that it uses a surface from a valve cover and a flap-retaining surface on a valve seat to mechanically hold the flap against the flap retaining surface and to position the flap relative to the seal surface to enable the flap to be pressed towards the seal surface in a substantially abutting relationship with it under any orientation of the valve.

1. Prior Art Does Not Teach or Suggest All Elements of Applicants' Invention

(a) Simpson's Failure to Teach or Suggest Applicants' Invention

Simpson describes a flap valve 13 in its Figure 2 that comprises a flexible circular flap member 15:

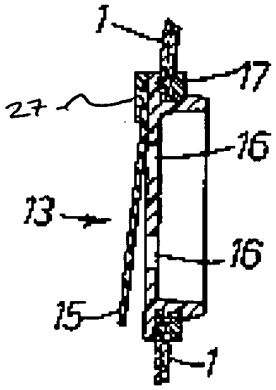

FIG. 2.

[Simpson Flapper Valve]

The flap member 15 is made of a plastic material and is arranged to cover a closed valve opening 13 during an inhalation and to flex away from those openings during an exhalation (p. 2, lines 37-42). To allow flexing of the flap member 15, a part of its peripheral portion — that is, a segment of the flap member — is fixed in position and the remaining part of the flap member is left free (p. 2,

lines 42-46). A part, identified by applicants' attorney using numeral 27, holds the flap against the valve seal surface. The valve is fitted in an aperture on the mask and is held in place by a retaining ring 17 (p. 2, lines 46-50). As shown in Simpson's Figure 1 reproduced above (see page 5), the valve 12 is disposed on the top portion 1 of Simpson's duck-bill or pouch-shaped mask.

Simpson fails to teach using a surface from a valve cover to press the flap against a flap-retaining surface. Simpson also fails to teach having the *flexible flap pressed towards a seal surface under any orientation of the valve.* An expert in the field of respirators and respirator components, David M. Castiglione, has provided evidence that establishes that the valve 13 shown in Figure 2 of Simpson does not have its flap 15 *pressed* against the seal surface in an abutting relationship with it when a wearer is neither inhaling nor exhaling. Castiglione states in paragraph 9 of his February 2, 2001 Affidavit (Exhibit A[4]) that "there is nothing that can be discerned from Figure 2 [of Simpson] or from the [Simpson] specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Another expert in the field of exhalation valves, John Bowers, (the inventor named in U.S. Patent 5,687,767) stated the following with respect to Simpson in paragraph 15 of his Declaration dated December 10, 2001 (Exhibit B):

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

Given the aligned relationship between the flap retaining surface and the seal surface, there is no force exerted upon the flap that would bias the flap against the seal surface. Simpson's flap 15 can only reside in mere contact with the seal surface in the closed position. Simpson therefore places the exhalation valve 12 on the top portion 1 of its pouch-shaped mask (see Fig. 1 of Simpson) so that gravity can hold the valve shut when the wearer is neither inhaling nor exhaling. Gravity,

[4] Exhibits are attached to the Amendment mailed June 24, 2002.

however, cannot hold the flexible flap against the flap-retaining surface in an abutting relationship with it when a fluid is not passing through the orifice *under any orientation of the filtering face mask.* In maintaining the rejection, the Examiner completely ignores the above Bower's statement. Although he addresses the testimony of Castiglione, the Examiner, in so doing, makes a number of logical, legal, and factual errors:

(i). Firstly, the Examiner improperly states that the Castiglione affidavit can be ignored because Simpson itself does not provide a disclosure that corroborates Castiglione's interpretation of how the Simpson valve operates:

> The Castiglione affidavit contends that the valve flap of Simpson et al. must rely on negative inhalation pressure to maintain a closed position is disagreed with because there is no disclosure in Simpson et al. which suggests such a requirement.[5]

This position is nonsensical. The fact that Simpson does not explicitly state that its valve relies on negative inhalation pressure to keep the valve closed does not mean that its valve does not operate in such a fashion. Simpson also does not state that the sun does not rise in the west, but this does not mean that the Examiner can summarily disagree with the position of an expert who confirms that the sun doesn't so rise. In short, there is no logical nor legal basis for ignoring the position of an expert simply because a reference exhibits silence on that particular subject.

(ii). Secondly, the Examiner relies on irrelevant and misplaced disclosures in Simpson to maintain his view that the Simpson flap is pressed against the valve's seal surface under any orientation to the valve:

> On the contrary, Simpson et al. fig. 3 clearly illustrates valve flap (14) being resiliently held in a closed position against knife edge sealing surfaces (19) thereby providing a clear teaching of a seal between the valve flap and valve seat during before the mask is donned. Further, Simpson et al. (page 1, lines 39-64 and page 2, lines 29-32) disclose that the mask is intended to filter harmful vapors (a function which cannot be accomplished while an exhalation valve is dangling open), that the mask includes an exhalation valve(s) located on portion (1, upper side) and/or portion (2, lower side) of the mask, that the exhalation valve(s) are intended to materially reduce the buildup of water vapor and that while the exhalation valve(s) may leak it is clear from the disclosure that they are not intended to leak. Therefore, in view of the disclosure as a whole, one of ordinary

[5] Office Action mailed October 2, 2002 at p. 11, third full ¶.

> skill could not conclude that the exhalation valve(s) of Simpson et al. would require negative inhalation pressure in order to remain in a closed position.[6]

Simpson's Figure 3 is not pertinent to maintaining the obviousness rejection. This figure discloses a button-style exhalation valve. It is not the same valve as the Figure 2 cantilevered valve, which is the valve that is used as the basis for maintaining the obviousness rejection. As such, the structure of the Figure 3 valve is not pertinent to the functioning of the Figure 2 valve. And in any event, the flap in Simpson's Figure 3 valve is also mounted in a straight line with the seal surface, and therefore also would not be pressed towards the seal surface in a substantial abutting relationship under any orientation of the valve. The Examiner's reference to Simpson's intent to "filter harmful vapors" is likewise irrelevant to the actual operation of the Simpson valve. Simpson's valve would remain closed during an inhalation: the negative inhalation pressure would surely cause the flap to be drawn against the seal surface. In fact, this is precisely what Simpson teaches (see page 2, lines 37-42). The time when an inhalation occurs is the most critical period for a valve to be closed. Otherwise contaminants can be drawn directly into the wearer's respiratory system. It is, however, not as critical for the valve to be closed under neutral conditions — that is, when there is no net inflow of air into the mask interior. Known masks like Simpson thus did not account for this. In fact, Simpson admits that its valves may leak and proposes the solution of using an "antechamber" to correct it (p.1, lines 58-64). Applicants find no disclosure in Simpson for securing the valve to portion 2 of the mask.[7] Even if so positioned, however, the valve still would not be placed directly in the path of the exhale flow stream. With respect to the Examiner's comment about "water vapor buildup", applicants also fail to locate any discussion in Simpson regarding how its valves "reduce the buildup of water vapor".

(iii). Thirdly, the Examiner ignores pertinent claim limitations when stating that gravitational forces would keep the valve closed:

> Applicant's assertion that the exhalation valve flap would dangle open responsive to gravitational forces even if accurate does not distinguish from Simpson et al. because if the exhalation valve of fig. 2 where located with portion #1 (upper portion) of the mask as illustrated in fig. 1 and as disclosed by Simpson et al. at page 2, lines 29-32, then by applicant's own reasoning the valve flap would

[6] Id.

[7] The closest that Simpson appears to disclose this is in claims 3 and 4.

> remain in the closed position due to gravitational forces until being subjected to the pressure of exhalation by a wearer.[8]

Applicants claims specify that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice *under any orientation of the valve*. Surely, gravity would not operate to keep the Simpson flap pressed towards the seal surface when the valve is in an inverted position. Apparently the Examiner is not giving significant appreciation to this limitation when evaluating the obviousness issue.

(iv). Fourthly, the Examiner commits legal error when he asserts that the Castiglione Affidavit is "insufficient" because the insertions made in it are not "based on actual physical inspection and comparison of the prior art device to the device of the instant invention as claimed." The Examiner bolsters this error when he states that Castiglione's testimony is not valuable because it is not based on "actual objective testing of the prior art device". Persons skilled in the respiratory art, particularly the exhalation valve art, like David M. Castiglione, are not required to — and do not need to — test an actual exhalation valve to arrive at conclusions regarding how the valve operates. The Simpson patent clearly shows a valve (in Figure 2) that does not have its flap 15 pre-stressed such that it is pressed against the seal surface. The valve shown in Simpson's Figure 2 has a flap-retaining surface that is in direct alignment with its seal surface. There is no need to test an actual sample of the device to come to Castiglione's conclusion. A simple visual examination of the above-reproduced figure, with an understanding of basic physical principals (or perhaps even without), can allow one to easily recognize that Simpson's flap is not biased towards the seal surface.

(b) Shindel's Failure to Teach or Suggest Applicants' Invention

Shindel also does not teach or suggest a structure that would cause the flexible flap to be pressed against a seal surface. Shindel's valve has a rim portion 6 that surrounds flap 7:

[8] Id. Id. at page 12, first ¶.

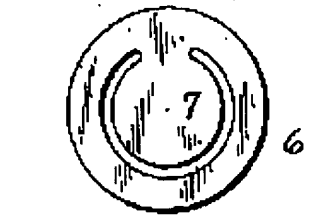

Fig. 5

[Shindel Flap]

A cut-out, identified by applicants' attorney using number 25 is provided in the valve. Because Shindel's valve is mounted flat on a circular boss 5 (see Fig. 2 below) and because Shindel's valve seat is in direct alignment with the point of mounting like Simpson, Shindel also does not present a structure that would cause flap 7 to be pressed towards the seal surface in an abutting relationship with it under any orientation of the valve:

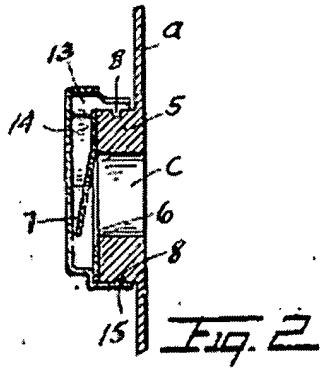

Fig. 2

[Shindel Valve]

Like Simpson, Shindel's flap would at best only reside flush against the seal surface.

2. No Evidence of Teaching or Suggestion to Combine Simpson with Shindel

The record lacks any evidence that a person of ordinary skill would have been motivated to combine the teachings of Simpson with those of Shindel. Simpson's Figure 2 shows a part 27 on the valve seat, which part holds the flap against a flap-retaining surface on the valve seat:

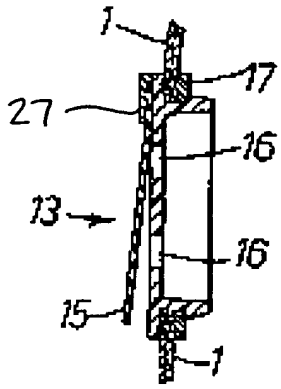

FIG. 2.

[Simpson's Valve]

Because Simpson uses this system for securing its flap to the valve seat, there is no reason why a person of ordinary skill would have been motivated to use a surface on a valve cover to hold the flexible flap against the flap-retaining surface on the valve seat. Although the Examiner states that "[i]t would have been obvious to modify the manner of attachment of the exhalation valve of Simpson et al. to provide a cover over the valve seat because it would have provided a simple arrangement with ready removability of the cover when desired and because it would have provided protection for the exhalation valve as taught by Shindel", this statement only expresses a reason why a person of ordinary skill might have used a valve cover on the Simpson valve. It does not provide any evidence as to why a person of ordinary skill would have been particularly motivated to use Shindel's valve cover.

3. Simpson and Shindel Provide Evidence for Lack of a Combination

The Simpson and Shindel documents each present very good evidence of a lack of motivation to combine their respective teachings. Shindel's technology was known to persons of ordinary skill long before the Simpson publication, yet Simpson did not employ the Shindel technology in its flapper-style exhalation valve. If the use of the particular structure necessary for holding the flap against the flap-retaining surface and causing it to be pressed towards the seal surface under any orientation would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve (this is only an assumption made for purposes of argument) — you would have expected a person skilled in the exhalation valve art to have used that technology in a

valve like Simpson's. But a very long time has passed since Shindel's publication in 1929 and its disclosure of a valve device for a respirator, yet its technology nonetheless did not find its way into a Simpson-type structure. If Shindel's technology provided benefits to the Simpson structure, the skilled artisan in the respirator art would have been expected to use it by the time of Simpson's publication. A prolonged existence of unused technology provides very good evidence of nonobviousness.[9] Simpson (published about 52 years after Shindel and filed more than about 12 years before the effective filing date of the present application) also did not use Shindel's technology. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the long time that has elapsed since Shindel's publication, and the failure to use this technology in a Simpson-type flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.[10]

4. Evidence of Copying Shows Nonobviousness

The copying of the technology of applicants' invention shortly after its publication further establishes its non-obviousness. As the Board is aware, the reviewing courts have relied on evidence of copying to find an invention to be not obvious to a person of ordinary skill.[11] For

[9] *See Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

[10] *In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

[11] See e.g., *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) (Copying is additional evidence of nonobviousness."); *Diversitech Corp. v. Century Steps, Inc.* 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) ("Copying is an indicium of nonobviousness, and is to be given proper weight."); *Dow Chemical Co. v. American Cyanamid Co.*, 816 F. 2d 617, 622, 2 USPQ2d 1350, 1355 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 849 (1987) (the conclusion that the claimed invention would not have been obvious is supported by evidence of commercial success and acts of the infringer in trying but failing to "develop the claimed invention and [then copying] it instead"); *Windsurfing International, Inc. v. AMF Inc.*, 782 F.2d 995, 1000, 228 USPQ 562, 565 (Fed. Cir. 1986), ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").

example, in *Specialty Composites v. Cabot Corporation,*[12] the Federal Circuit stated that "[c]opying the claimed invention, rather than one in the public domain, is indicative of unobviousness."[13] Secondary considerations like copying must always be considered in connection with an obviousness determination.[14]

Although Moldex Metric subsequently introduced a valve product that uses applicants' invention, the Examiner seemed to give little weight to this evidence in considering the outstanding rejection. The Moldex valve is of record as Exhibit C in the Amendment mailed June 24, 2002. An examination of this article reveals that its valve cover has a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in a substantial abutting relationship under any orientation of the valve. This product is described in U.S. Patent 6,047,698 to Magidson et al., which was filed on August 20, 1998, after applicants' invention was publicly disclosed. But Moldex' earlier reveals that button-style valves were used on Moldex' filtering face masks (see U.S. Patent 4,873,972). And the more recent '698 Magidson patent (which describes the Exhibit C valve) states the benefits of using the technology claimed in this patent application:

> The valve member 16 includes an off center arm 24 which cooperates with a shelf portion 26, located within the valve seat 22, to lock the flexible flap 20 off center in position within the valve 14 when the two half members 16 and 18 are closed, as shown by arrow 28, around a hinge portion 30.

(Column 2, lines 15-21). The '698 Moldex patent goes on to state that the flap is pushed into sealing engagement with the valve seat when a fluid is not passing through the orifice. Moldex illustrates the technology in Figs. 3 and 4:

[12] 6 USPQ2d 1601, Fed. Cir. 1988.
[13] *Id.* at 1608.
[14] *In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983) ("If, however, a patent applicant properly presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness."); see also *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) ("As discussed more fully below, the district court erred in specifically declining to consider the objective evidence of nonobviousness."); Manual of Patent Examining Procedure 2100-90 (Feb. 2000).

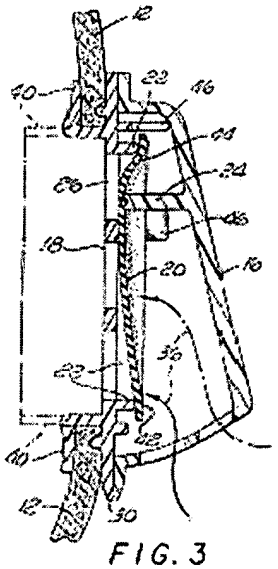

FIG. 3

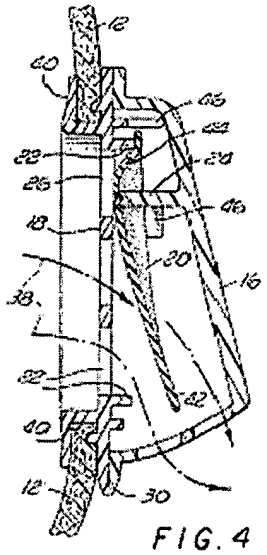

FIG. 4

Another product of similar structure, which also was introduced after the publication of applicants' invention, is shown in Exhibit D of the June 24, 2002 Amendment. This mask product is sold by Survivair.

The use of the technology of appellants' invention by other respiratory product manufacturers after publication of applicants' invention provides very good evidence that the invention would not have been obvious to a person of ordinary skill. Although Simpson's and Shindel's teachings had been known for many years before applicants' filing date, there is no evidence that any competitor had previously introduced a product that is similar to the exhalation valve that is described and claimed in the present application. The introduction of such products after the publication of the technology of applicants' invention, however, further establishes that person's skilled in the filtering face mask art surely did not find obvious the subject matter of applicants' invention.

5. Summary of Nonobviousness Based on Simpson and Shindel

Applicants' invention would not have been obvious to a person of ordinary skill because the primary reference to Simpson fails to teach or suggest the basic elements of applicants' invention. Simpson does not have the flap held against a flap-retaining surface by pressure from a surface on the valve cover. Simpson's flap also is not pressed against the seal surface. Simpson therefore places its exhalation valve on the top portion of its pouch-shaped mask so that gravity can keep the flap closed under neutral conditions. In this position, however, Simpson's valve may fog the

wearer's eyeglasses, and it cannot take full advantage of the exhaled airflow momentum to open the valve. Further, the record is devoid of any teaching, suggestion, or motivation to combine the teachings of Simpson and Shindel. Indeed, Simpson and Shindel present very good evidence for a lack of motivation to combine their teachings because Simpson already has its flap mounted suitably to the valve seat by a different method. Shindel's technology also was never mentioned in Simpson or any other exhalation valve document despite it being known for many years. But even if the references would have been combined by a person of ordinary skill, Shindel does not teach how to get the flap to be pressed against the seal surface under neutral conditions and any orientation of the valve. These two documents also do not teach or suggest the benefits that applicants' invention may provide. Because neither has a preload on their flap, there is great risk that the flap will remain open when subject to the adhesive nature of moisture and saliva. In addition, the copying of the technology claimed in the present application by competitors, after this publication of applicants' invention, also shows that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.

Finally, even if we make the assumptions that the record does suggest that a person of ordinary skill would have been motivated to use Shindel's valve cover and means for securement in Simpson, and if we then totally ignore the nonobvious evidence with respect to (a) Simpson not needing Shindel's approach, (b) the long time passing since Shindel's publication, and (c) the copying of applicants' technology, the record with respect to this rejection is still devoid of any teaching or suggestion for having the flexible flap pressed towards the seal surface in a substantial abutting relationship. **The Examiner states on page 3 of the Office Action mailed May 9, 2002 that Simpson discloses this feature at page 2, lines 37-50, but applicants find no such teaching at that location in the Simpson patent.** To the contrary, this portion of the Simpson patent only indicates that the flap covers the valve opening 16 during an inhalation. It does not indicate that the flap is pressed towards the seal surface when a fluid is not passing through the orifice. **In a subsequent Office Action mailed October 2, 2002, the Examiner wholly neglects to cite any disclosure in Simpson or Shindel which teaches or suggests this limitation. Thus, the Examiner is still apparently relying on page 2, lines 27 to 50 of Simpson for this disclosure (which clearly does not teach the missing feature of applicants' invention) or the record, as it presently stands for this obviousness rejection, is totally devoid of any evidence of a teaching**

of the missing limitation. Accordingly, applicants respectfully ask the Examiner to clarify the record for purposes of this appeal and identify where, in Simpson or Shindel, there is a teaching of a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve. If such a teaching cannot be identified, then the Examiner should withdraw this rejection. It is not legally proper for the Examiner to maintain an obviousness rejection without identifying where all features of present invention are disclosed. It also is not proper for the Examiner to disregard — or substitute his viewpoint for — the evidence supplied by persons who are skilled in the technology at hand.[15] The MPEP is in accord:

> Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient.[16]

Thus, for the above reasons, the rejection based on Simpson and Shindel must be reversed.

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[15] *See, In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967). Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); *see also In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

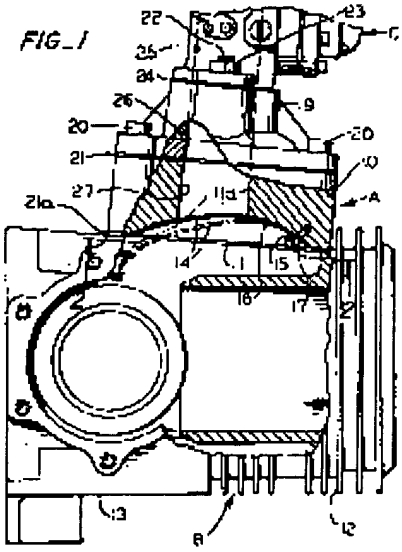
[16] MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

Issue 2 - Obviousness Based on Simpson, Shindel, and McKim

Claims 37-39[17] define patentable subject matter for the reasons presented above with respect to the rejection based on Simpson and Shindel and also for the following reasons:

1. McKim is Not Analogous Art

The secondary reference, U.S. Patent 3,191,618 to McKim, cannot be applied as a reference against applicants' invention because the McKim patent does not describe analogous art. McKim discloses a curved seat reed valve for a 2-cycle engine:



[McKim]

The reed valve includes a valve reed 14 of spring sheet materials such as shim stock (col. 1, lines 60-61). The spring sheet material is secured by an anchor bar 15 and screws 17 to a curved seat 18 that is formed on the inner-engine side of the valve bock 10 (col. 1, lines 61-63). Curvature of the seat 18 corresponds to the normally flexed condition of the valve reed 14 when it is flexed laterally from its normally straight position as shown in Figure 3 (col. 1, lines 64-66). The normally flexed curvature of the reed is provided to eliminate float, or flutter from bounce when closing (column 1, lines 19-24; column 2, lines 55-62). The McKim valve is fashioned for use on high-speed engines, for example one that will turn at a speed on the order of 10,000 to 12,000 revolutions per minute (col. 2, lines 55-62). For a more modest speed, for example, 5,000 or 6,000 rpms, the curvature of

[17] McKim is only being cited for the subject matter of claim 37. Accordingly applicants will only address this rejection with respect to this claim and the claims that depend from it (38 and 39).

the valve seat may be reduced to provide a freer, fuller opening of the valve at the lower speeds (column 2, lines 62-65).

As the Board is aware, a reference is not analogous and thus not relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably pertinent to the particular problem that confronted the inventor.[18] Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed valves. McKim therefore does not satisfy part (1) of the two-part test. The Examiner does not dispute this. Thus, we only need to evaluate McKim under part (2) of the test.

In the leading case that deals with "analogousness" under part (2) of the test, the Federal Circuit has explained that the USPTO needs to consider the purposes of the reference disclosure and the invention in determining whether a reference is reasonably pertinent to the particular problem that confronted the inventor:

> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added).[19]

In developing their invention, applicants sought to produce an exhalation valve that minimized exhalation pressure needed to open the valve and that allowed a greater percentage of exhaled air to be purged through the exhalation valve to improve wearer comfort while also allowing the valve to remain closed under any orientation (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce

[18] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).
[19] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure so that a greater percentage of exhaled air can be purged from the mask interior while also enabling the valve to remain closed under any orientation. As stated in the Bowers Declaration, investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

> In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

Bowers' Affidavit, paragraphs 11-13 (Exhibit B). Another person skilled in the field of exhalation valves for filtering face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

> My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The

reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.

Filtering face masks posses the problem of creating a warm, moist, high CO_2 content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO_2 content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit, paragraphs 8-10 (December 10, 2001) (Exhibit D).

The Bowers and Fabin declarations discussed above explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention. Because the purpose of appellants' invention is not pertinent to the problem that McKim dealt with, namely float or bounce, the second prong of the test for qualifying as an analogous reference also has not been met. A

person possessing ordinary skill in the art of filtering face masks that use exhalation valves therefore would not reasonably have been expected to solve the problem of lowering the airflow resistance force needed to open an exhalation valve through considering a reference that deals with eliminating float or bounce in a valve reed in a 2-cycle gasoline engine.

The Federal Circuit has clearly stated that when the reference "is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it" and therefore it would not be analogous.[20] **Accordingly, if the Examiner cannot establish that float or bounce is a problem that persons of ordinary skill in the exhalation valve art sought to overcome, McKim should not be an analogous reference, and therefore the rejection based on McKim should be withdrawn.**

In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation (to channel flow in a desired direction) and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank. Although both Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention.* Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved, namely, preventing loss of stored product in a tank's dead volume. The court also found that the subterranean formation of Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks.

As in *In re Clay*, the McKim reference also does not have the same purpose as the applicants' invention, it does not operate under the same temperature and pressure, and it does not function like the claimed invention. Float or bounce is a problem that occurs when a two-cycle engine operates at high rpms (10,000 to 12,000 rpms). It is not a problem that occurs in an exhalation valve that opens and closes in cadence with a person's breathing, which is about 20 to 60 cycles per minute. And internal combustion engines, of course, operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a

[20] *Id.*

person's lungs but by gasoline combustion. Further, McKim's valve is used for intake while the present valve is used for exhaust.

Applicants accordingly encourage the Examiner to carefully consider the *In re Clay* decision.[21] A summary of the facts are provided below for ease of reference:

[21] See also *SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177_ (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

In re Clay	**Result: reference not analogous**					
	Description	***Problem to be Solved***	***Purpose***	***Operating Conditions***	***Similarities***	***Differences***
Clay	use of gel to displace liquid product from tank dead volume	preventing loss of stored product to tank dead volume	to displace liquid product from dead tank volume	• subterranean rock • high temps (115°C) and bore pressures	both used in petroleum industry	different purposes and operating under different temperatures and pressures
Prior Art Sydansk	use of gel to fill anomalies in natural oil-bearing conditions	recovering oil from rock	to channel flow in a desired direction	• made storage tank • ambient temp and pressure		
In re Japuntich et al.	**Result: not yet decided**					
Applicants' Invention	use of a new flapper-style exhalation valve in a filtering face mask	keeping valve closed under any orientation while allowing low pressure drop during an exhalation	to allow valve to open easier during an exhalation but remain closed under neutral conditions	• exhale valve on face mask body • body temperatures • low pressures • cadence of person's breathing	both relate to valves	different purposes and operating under different temperatures, pressures, and speeds
McKim	use of new reed intake valve in a two-stroke engine	stopping flutter or bounce of reed valve while operating under high RPM conditions	to eliminate float or bounce of valve reed to improve power and efficiency of engine	• intake valve on 2-cycle engine • high temps • high pressure • high speeds (10-12,000 rpms)		

2. McKim Does Not Describe a Flexible Flap

Even if McKim is found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve disclosed in McKim would not answer the required properties of appellants' valve. As such, there would be no reason for a person of ordinary skill to consult or trust McKim's teachings on an exhalation valve.

There is no evidence that the McKim reed valve would demonstrate the required flexibility of appellants' flexible flap. Appellants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and

viewed from a side elevation (see, e.g., Fig. 5)."[22] The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve.[23] This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

> Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001) (Exhibit E). Because McKim's valve reed is so structurally different — namely, so much stiffer than — the flexible flap that is used in applicants' invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for a flexible flap that is used on an exhalation valve. The Examiner discounts this argument by holding that "no particular degree of flexibility is quantitatively and/or structurally defined in any of the claims of the instant application." This position is not correct: applicants have defined the term "flexible" to mean that "the flap can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see e.g., FIG. 5)."[24] As stated by Betts in his Declaration, if secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation." In addition to McKim's failure to describe a

[22] Appellants' specification at page 7, lines 11-14.
[23] In an interview held with Examiner Lewis and the SPE Examiner Weiss in another continuation application in this series, Examiner Weiss agreed with applicants' attorney that a reed valve in a 2-cycle engine would not be flexible like the flap of the present invention.
[24] Id. at lines 23-25.

flexible flap, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) are so remarkably different from the conditions under which an exhalation valve operates (lung pressure, exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable in an invention like the one under consideration here. Thus, the mounting requirements for the McKim cannot so easily be transferred to an exhalation valve like Simpson's without some clear teaching or suggestion to do so.

3. No Evidence of Teaching of Suggestion to Combine McKim with Simpson and Shindel

The record is devoid of any teaching, suggestion, or motivation to combine the pertinent teachings of Simpson and McKim. As the Board is aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.[25] The suggestion to make the combination must come from the prior art.[26] It is not enough to simply identify each claimed element in the prior art.[27] "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."[28]

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned so much with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. Although Shindel is primarily concerned with producing a new exhalation valve, McKim's teachings are for providing a curved intake reed valve seat on a 2-cycle gasoline

[25] *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").
[26] *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").
[27] *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").
[28] *In re Lee*, 61 USPQ 1431, 1433 (Fed. Cir. 2002).

engine to reduce float or bounce. Nonetheless, the Examiner stated in the Office Action mailed October 3, 2002, that "it would have been obvious to further modify the flexible valve flap and seat of Simpson et al. (fig. 2) to make it curved because it would have provided for quick seating, in an effective manner and without float or bounce after each opening as taught by McKim." **The Examiner, however, has not cited any authority for his view that eliminating float or bounce would be a problem that persons skilled in designing exhalation valves would seek to overcome.** Although not necessary to overcome the rejection, appellants have nonetheless responded to this unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers stated that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, although the "bounce or float" motivation cited in both the October 3, 2002 Office Action and the September 10, 2001 Office Action for combining the two references does not exist, the Examiner, in the October 3, 2002 Office Action, has ignored the evidence of record from the Bowers Affidavit and has put a further twist on the reason or motivation to combine by stating that:

> one of ordinary skill having possession of the prior art to Simpson et al. and McKim which clearly teaches nonaligned mounting of a valve flap in order to achieve effective sealing would suggest an answer to the problem of how to prevent accidental valve opening and efficient sealing between inhalation and exhalation.[29]

Apparently, the Examiner is either properly backing away from his previous position that the references would have been combined to eliminate "float or bounce" or the Examiner is now citing an additional reason, namely, "prevent[ing] accidental valve opening and [encouraging] efficient sealing". This latter reason, however, appears to be one that again is wholly the Examiner's creation because there is nothing in the record to support this position. McKim does not describe its flap mounting structure "to achieve effective sealing [under neutral conditions]". McKim teaches its flap mounting structure to eliminate flutter, float, or bounce in a 2-cycle engine — a problem that has been shown to have no pertinence to the operation of an exhalation valve. McKim therefore would have not provided a motivating reason to address or answer the problem of improving pressure drop, while providing good sealing of an exhalation valve. And Simpson, while

[29] Office Action of October 3, 2002 at page 14, ¶ 3.

recognizing that its valve may leak, suggests using an "antechamber" as a solution. This presents very good evidence of the non-obviousness of the combination. In addition to not being supported by the record, the Examiner's position, quoted above, also runs counter to his earlier position that Simpson does (somehow) describe a flap that is pressed against the seal surface under any orientation of the valve. And it turns evidence of nonobviousness on its head. To the extent that the Simpson and Shindel valves do not remain closed under any orientation, this fact presents evidence of nonobviousness — not obviousness.[30] As the record presently stands, only applicants describe the need to provide a low pressure drop, cantilevered valve that seals effectively under any orientation. Applicants' teachings, of course, cannot be properly used against them to reject their own invention. Accordingly, until sound evidence is placed in the record, the present combination cannot be properly sustained.[31]

The Examiner's continuing inability to cite any objective prior art evidence in support of his reason to combine is legal error. As the Board is aware, obviousness rejections based on combinations of references are improper when there is no evidence within the four corners of the record, to support the reasoning behind making the combination.[32] It is not enough to merely recite broad conclusions.[33] Applicants therefore respectfully request that the Examiner clarify the record in regard to the known motivating reason for making the combination. Because if the Examiner is no longer relying on his belief that "float or bounce" is a problem that needs to be overcome in the exhalation valve art, this should be made clear. But if the Examiner is still relying on the same basis, then applicants submit that the Examiner is then committing legal error in disregarding the testimony of Bowers. As the Board is aware, the reviewing courts have stated on numerous

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[30] *In re Dien,* 152 USPQ 550, 551 (CCPA 1967) ("The mere existence ... of an unsatisfactory process and the attendant incentive to seek improvement do no negative patentability.').

[31] *See, Lee,* 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.

[32] *See, Lee,* 61 USPQ2d at 1433 ("The factual inquiry whether to combine references must be thorough and searching." It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.").

[33] *In re Dembiczak,* 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'.").

occasions that it is not proper for Examiners to disregard — or substitute their viewpoint for — the evidence supplied by persons who are skilled in the technology at hand.[34] If the Examiner is relying on some other unstated motivating factor, then evidence of it, supported by the art of record as a whole, should be furnished so that applicants can have an opportunity to properly respond.

4. Evidence of Record Suggests Combination is Not Proper

The Simpson, Shindel, and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose flapper-style valves (albeit in entirely different fields). If the use of a curved flexible flap, and the particular structure necessary for creating that curvature and causing the flap to be pressed towards the seal surface, would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's. The Board should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this time span. If this aspect of the applicants' invention would have been obvious to a person of ordinary skill, then the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good

[34] *See, In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967). Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); *see also In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

evidence of nonobviousness.[35] Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.[36]

5. Prior Art Fails to Suggest Advantage of Applicants' Invention

An invention's advantages must be considered under the "invention as whole" concept set forth in 35 USC § 103.[37] Advantages that are not appreciated by the prior art also provide very good evidence of nonobviousness.[38] In the present case, applicants' invention possesses the benefit of achieving a low pressure drop valve while also preventing the influx of contaminants through the valve under any orientation. The Simpson and Shindel valves, however, only protect the wearer at the most critical time — during an inhalation. When a wearer of either mask inhales, the flap becomes firmly pressed against the seal surface. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, gravity can cause the flap to droop away from the seal surface. Simpson and Shindel's valves therefore may allow contaminants to enter the mask interior in this instance. To counter this problem, Simpson mounts its valve on the top of the mask body so that gravity can be used to keep the flap closed under neutral conditions. If the valve was mounted to the underside of the mask, the flap would dangle away from the seal surface. The

[35] *See Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

[36] *See In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

[37] *In re Papesch*, 137 USPQ 43 (CCPA 1963).

Simpson and Shindel valves, unlike applicants' invention, therefore, have limited suitable mounting positions on the mask body when considering the need to halt contaminant influx under neutral conditions. But even if either valve was mounted to the top of the mask body to take advantage of gravity for this purpose, they, still could allow contaminants to enter the mask interior when the user fully tilts their head downward. Further Simpson and Shindel do not teach or suggest valves that have a pre-load on the flap. As such, these valves can remain open when moisture of saliva causes the flap to stick to another surface like a valve cover.

Applicants teach persons of ordinary skill how to make a low pressure drop flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. Applicants achieve this through the use of a single flexible flap that has one free portion, one stationary portion, and a peripheral edge, where the peripheral edge has a stationary and free segments which are associated, respectively, with the stationary and free portions of the flap, and through use of a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve. Applicants' valve also does not have to be disposed on the top side of the mask, and there is little risk that the flap will get stuck in the open position. Applicants' invention enables the valve to be disposed on the mask directly in the path of the exhale flow stream — that is, centered on the front of the mask (see Fig. 1) — so that the valve can use the full momentum of the exhaled air stream to lift the flap from the seal surface.

As indicated in paragraphs 15 and 16 of the Bowers Declaration (Exhibit B), the Simpson flap would droop open when the wearer tilts their head downward:

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

[38] *See, e.g., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

> The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

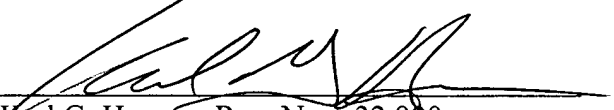
The failure of Simpson to appreciate the benefits of applicants' invention and instead teach a more deficient construction further establishes the nonobviousness of applicants' invention. McKim, of course, does not address these benefits to the slightest degree because it is a reference that resides in an entirely different field and deals with entirely different problems under entirely different conditions. In short, the prior art does not teach or suggest the construction of applicants' valve, and it does not appreciate the benefits that that construction invention can provide. Under such circumstances, Simpson, Shindel, and McKim would have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.[39]

IX. CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application under 35 USC § 103. Please reverse the decision below.

Respectfully submitted,

January 17, 2003
Date

By: 
Karl G. Hanson, Reg. No.: 32,900
Telephone No.: 651-736-7776

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833

[39] *See, e.g., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

APPENDIX

34. The filtering face mask of claim 68, wherein the valve seat is made from a relatively light-weight plastic that is molded into an integral one-piece body.

35. The filtering face mask of claim 34, wherein the valve seat has been made by an injection molding technique.

36. The filtering face mask of claim 68, wherein the seal surface is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface.

37. The filtering face mask of claim 68, wherein the flexible flap would normally assume a flat configuration when no forces are applied to it but has a curved profile when viewed from a side elevation.

38. The filtering face mask of claim 37, wherein the flexible flap is elastomeric and is resistant to permanent set and creep.

39. The filtering face mask of claim 37, wherein the flexible flap is made from an elastomeric rubber.

40. The filtering face mask of claim 68, wherein the flexible flap has a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hours at 70 °C.

41. The filtering face mask of claim 40, wherein the flexible flap provides a leak-free seal according to the standards set forth in 30 C.F.R. § 11.183-2, July 1, 1991.

42. The filtering face mask of claim 68, wherein the flexible flap is made from a crosslinked polyisoprene.

43. The filtering face mask of claim 68, wherein the flexible flap has a Shore A hardness of about 30 to 50.

44. The filtering face mask of claim 68, wherein the flexible flap has a generally uniform thickness of about 0.2 to 0.8 millimeters.

45. The filtering face mask of claim 44, wherein the flexible flap has a generally uniform thickness of about 0.3 to 0.6 millimeters.

46. The filtering face mask of claim 45, wherein the flexible flap has a generally uniform thickness of about 0.35 to 0.45 millimeters.

47. The filtering face mask of claim 68, wherein the one free portion of the flexible flap has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

48. The filtering face mask of claim 47, wherein the flexible flap is greater than one centimeter wide.

49. The filtering face mask of claim 48, wherein the flexible flap is 1.2 to 3 centimeters wide and is about 1 to 4 centimeters long.

50. The filtering face mask of claim 68, wherein the stationary segment of the peripheral edge of the flexible flap includes about 10 to 25 percent of the total peripheral edge of the flexible flap, with the remaining 75 to 90 percent being free to be lifted from the seal surface.

51. The filtering face mask of claim 68, wherein the valve seat includes a flange that provides a surface onto which the exhalation valve can be secured to the mask body, and wherein the flange extends 360 degrees around the valve seat where the valve seat is mounted to the mask body.

52. The filtering face mask of claim 68, wherein the flexible flap is positioned on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

53. The filtering face mask of claim 68, wherein the mask body is cup-shaped and comprises (1) at least one shaping layer for providing structure to the mask, and (2) a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

54. The filtering face mask of claim 68, wherein a high percentage of the exhaled air is purged through the exhalation valve.

55. The filtering face mask of claim 68, wherein at least 60 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

56. The filtering face mask of claim 55, wherein at least 73 percent of the total airflow flows through the exhalation valve under a normal exhalation test.

58. The filtering face mask of claim 68, wherein the exhalation valve is positioned on the mask body substantially opposite to a wearer's mouth, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

60. The filtering face mask of claim 68, wherein the shape of the orifice does not wholly correspond to the shape of the seal surface.

61. The filtering face mask of claim 68, wherein the valve cover has an opening that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation.

62. The filtering face mask of claim 61, wherein the opening in the valve cover is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

63. The filtering face mask of claim 62, wherein the valve cover and its opening direct exhaled fluid flow downwards when the mask is worn on a person.

64. The filtering face mask of claim 63, wherein the valve cover has fluid-impermeable sidewalls.

65. The filtering face mask of claim 63, wherein the opening in the valve cover is at least the size of the orifice in the valve seat.

66. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is surrounded by the seal surface; and

(iii) a flap-retaining surface; and

(2) a single flexible flap that has a stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person and viewed from the front; and

(3) a valve cover that is disposed over the valve seat and that comprises a surface that mechanically holds the flexible flap against the flap-retaining surface, wherein the flexible flap is held against the flap-retaining surface and is positioned relative to the seal surface such that the flap is pressed towards the seal surface in a substantial abutting relationship therewith under any orientation of the valve when a fluid is not passing through the orifice.

67. The filtering face mask of claim 66, wherein the valve cover is secured to the valve seat by a friction fit to a wall of the valve seat.

68. A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is surrounded by the seal surface; and

(iii) a flap-retaining surface; and

(2) a single flexible flap that has a stationary portion and only one free portion and a peripheral edge that extends 360° about the flap and that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person and viewed from the front; and

(3) a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where the flexible flap is mechanically held against the flap retaining surface being located off center relative to the flap.

69. The filtering face mask of claim 68, wherein the valve cover is secured to the valve seat by a friction fit to a wall of the valve seat.

70. The filtering face mask of claim 68, wherein the valve cover has fluid-impermeable opposing sidewalls that support a fluid impermeable ceiling, and wherein the valve cover has an opening that is disposed directly in the path of fluid flow, the fluid-impermeable sidewalls and the ceiling and the positioning of the opening in the valve cover causing fluid flow to be directed downwardly away from a wearer's eyes during an exhalation when the mask is worn by a person.

71. The filtering face mask of claim 70, wherein the flexible flap is mechanically clamped between the surface on the valve cover and the flap-retaining surface.

72. The filtering face mask of claim 68, wherein the flap-retaining surface is not disposed substantially in the path of the exhale flow stream.

73. The filtering face mask of claim 68, wherein the orifice includes a plurality of openings, which plurality of openings are disposed within the orifice beneath where the flexible flap is mounted to the valve seat when viewing the filtering face mask from the front in an upright position.

74. The filtering face mask of claim 73, wherein the exhaled air passes primarily through the plurality of openings within the orifice during an exhalation by a wearer of the mask.

75. The filtering face mask of claim 74, wherein the flap-retaining surface is located outside the region defined by the plurality of openings.